REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the following remarks:

DISPOSITION OF CLAIMS

Claims 1-6, 8-44, and 61-63 are pending in this application.

REJECTIONS UNDER 35 U.S.C. §103

Claims 1-6, 8-44, and 61-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wong et al. (U.S. Patent No. 6,419,952) in view of Dong et al. (U.S. Patent No. 5,800,422). This rejection is respectfully traversed.

Normally, "it is not inventive to discover the optimum or workable ranges by routine experimentation." See, In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (C.C.P.A. 1955). However, a patent can be obtained for the claimed critical range if the "results of optimizing a variable" are "unexpectedly good." See, In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8 (C.C.P.A. 1977). As the Federal Circuit has explained, "[o]ne way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of 'unexpected results,' i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary of skill in the relevant art would have found surprising or unexpected." See, In re Soni, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995). It is well settled that unexpected results must be factual evidence and that "[m]ere argument or conclusory statements in the specification does not suffice." See, In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1994).

In Example 1 of Wong et al., a coating solution formed as a suspension included methyl cellulose (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in a weight ratio of approximately 8/25/1, where methyl cellulose is 0.4% of the coating suspension. In Example 4 of Wong et al., a coating solution formed as a suspension included hydroxyethyl cellulose (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in a weight ratio of 3/2.9/9.1 (0.3/0.3/1). In Example 8 of Wong et al., a coating solution formed as a suspension included hydroxyethyl cellulose (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in

a weight ratio of 18.8/30.6/50.6 (0.4/0.6/1). In Examples 4 and 8 of Wong et al., the amount of film former in the coating solution is not disclosed.

In Example 1 of Dong et al., an osmotic layer included hydroxypropylmethyl cellulose E-5 (film former), sodium carboxymethylcellulose (osmopolymer), and sodium chloride (osmotic agent) in a weight ratio of approximately 5/58.75/30 (0.17/1.96/1), where hydroxypropylmethyl cellulose E-5 is 5 wt% of the osmotic layer. If the examples disclosed in Wong et al. and Dong et al. are considered as defining the bounds of the variables of the coating solution/osmotic layer in Wong et al. and Dong et al., and if Wong et al. is properly combinable with Dong et al., then Wong et al. and Dong et al. may be considered to teach a coating suspension/osmotic layer including 0.3:1 to 25:1 osmopolymer to osmotic agent and 0.4 wt% to 5.0 wt% film former.

Claim 1 recites a coating suspension for an expandable osmotic layer of a dosage form which comprises an osmopolymer, an osmotic agent, a film former, and a two-part solvent system. The coating suspension includes about 5 wt% to about 7 wt% of the film former. The ratio of osmopolymer to osmotic agent in the coating suspension is about 0.5:1 to about 0.7:1. There is an overlap in the claimed range and the combination of Wong et al. and Dong et al., as described above. The following is a factual showing of the existence of unexpected results in the ranges recited in claim 1.

The applicant would like to draw the Examiner's attention to Examples 1 and 2 in the instant application. In these examples, capsules containing liquid active agent formulation were over-coated with eight coating suspensions under dry or wet process conditions to form intermediate dosage forms. The composition of the coating suspensions are detailed in Table 2 (FIG. 5) of the instant application. For the Examiner's convenience, the composition of the coating suspensions are reproduced in Table A below, along with the ratio of osmopolymer to osmotic agent and whether the coating suspension satisfies all the limitations of claim 1 or not. It should be noted that all the coating suspensions listed in Table A have osmopolymer to osmotic agent ratio within the range recited in claim 1 but not all the coating suspensions have film former amount within the range recited in claim 1. It is further noted that the coating suspensions which do not satisfy all the limitations of claim 1 represent the closest prior art and overlap with the combination of ranges taught by Wong et al. and Dong et al. As stated by the Federal Circuit, "[w]hen unexpected results are used as evidence of nonobviousness, the results

must be shown to be unexpected compared with the closest prior art." See, In re Baxter Travenol Labs, 952 F. 2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991).

Table A

Coating Suspension	NACMC (osmopolymer)	NATROSOL (film former)	NaCl (osmotic agent)	WATER	ETHANOL	NACMC:NACL	SATISFIES CLAIM 1
24_12	4.9	3	8.1	62.7	21.3	0.6:1	NO
24_13	4.9	3	8.1	62.7	21.3	0.6:1	NO
24_14	4.1	5	6.9	62.7	21.3	0.6:1	YES
24_15	4.1	5	6.9	62.7	21.3	0.6:1	YES
24_16	4.9	3	8.1	65.3	18.7	0.6:1	NO
24_17	4.9	3	8.1	65.3	18.7	0.6:1	NO
24_18	4.1	6	6.9	65.3	18.7	0.6:1	YES
24_19	4.1	5	8.9	65.3	18.7	0.5:1	YES

Table 2 (FIG. 5) of the instant application shows the percentage of cracked intermediate dosage forms resulting from each coating run using the coating suspensions above. None of the coating suspensions according to the claimed invention produced cracked intermediate dosage forms under dry and wet process conditions. Coating suspensions 24_13 and 24_17 produced cracked intermediate dosage forms under wet process conditions but not under closely-monitored dry process conditions. The intermediate dosage forms were then over-coated with a semipermeable composition. The intermediate dosage forms coated with coating suspensions 24_13, 24_16, and 24_17 cracked when over-coated with semipermeable compositions under dry and wet process conditions. None of the intermediate dosage forms coated with coating suspensions according to the claimed invention cracked when over-coated with a semipermeable composition under dry and wet process conditions.

In the preceding paragraphs, applicant has compared the claimed invention with the closest prior art. As shown factually above and in the specification of the instant application, the combination of claimed ranges recited in claim 1 exhibit unexpected results when compared to the closest prior art. The unexpected result is that the coating suspension according to the claimed invention produces intermediate dosage forms that are resistant to cracking under both dry and wet process conditions. The coating suspension according to the claimed invention thus

facilitates commercial production of dosage forms incorporating a coated expandable osmotic layer. The Federal Circuit has explained, "when an applicant demonstrates substantially improved results" and "states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary." See, In re Soni, 54 F. 3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995).

From the foregoing, a showing of unexpected results has been made with respect to claim 1. Absent any evidence to the contrary, claim 1 is patentable over Wong et al. in view of Dong et al. Withdrawal of the rejection of claim 1 over Wong et al. in view of Dong et al. is respectfully requested. Claims 2-6 and 8-44, being dependent from claim 1, are likewise patentable in view of the foregoing arguments. Claims 61-62 recite a method of making a dosage form using the coating suspension recited in claim 1 and are patentable in view of the foregoing arguments. Withdrawal of the rejection of claims 2-6, 8-44, 61, and 62 is respectfully requested.

CONCLUSION

Applicant believes that this paper is fully responsive to the advisory action dated September 18, 2006, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC3162R1).

Respectfully submitted,

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